

JUL - 7 2004

K641606

**510 (k) SUMMARY**

**SPONSOR:** Boston Scientific Corporation  
One Boston Scientific Place  
Natick, MA 01760

**CONTACT PERSON:** James McMahon  
Senior Regulatory Affairs Specialist

**DEVICE:**

**Trade Name:** Extractor™ RX Retrieval Balloon  
**Common Name:** Catheter, Biliary, Diagnostic  
**Classification:** Class II per 21 CFR Part 876, Section

**PREDICATE DEVICE:** Extractor™ RX Retrieval Balloon

**DESCRIPTION:** The Boston Scientific Extractor™ RX Retrieval Balloon is a stone retrieval balloon catheter used for biliary stone retrieval.

**INTENDED USE:** The Boston Scientific Extractor™ RX Retrieval Balloon is intended to remove stones from the biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.

**COMPARISON OF CHARACTERISTICS:** The modified device is substantially equivalent to the predicate device, as they have the same operating principal and intended use. In addition, the results of design control activities do not raise any new issues of safety or effectiveness.

**PERFORMANCE DATA:** FDA's "Guidance for the Content of Premarket Notifications", and the results of physical comparison and functional testing support a determination of substantial equivalence for the modified device when compared to the predicate device. The modified device is substantially equivalent to the currently marketed Boston Scientific Extractor™ RX Retrieval Catheter in terms of performance characteristics, biocompatibility, and intended use.



JUL - 7 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. James D. McMahon  
Senior Regulatory Affairs Specialist  
Boston Scientific Corporation, Endoscopy  
One Boston Scientific Place  
NATICK MA 01760

Re: K041606  
Trade/Device Name: Extractor™ RX Retrieval Balloon  
Regulation Number: 21 CFR §876.5010  
Regulation Name: Biliary catheter and accessories  
Regulatory Class: II  
Product Code: 78 FGE  
Dated: June 14, 2004  
Received: June 15, 2004

Dear Mr. McMahon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

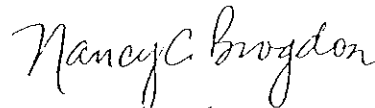
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: ~~To be determined~~ K041606

Device Name: Extractor™ RX Retrieval Balloon

Indications For Use: Indicated for use endoscopically to remove stones from the biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.

Prescription Use   X    
(Part 21 CFR 801 subpart D)

AND/OR

Over the Counter Use             
(21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Broglon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K041606